

REMARKS

The undersigned wishes to thank the Examiner for his time and courtesy during the telephonic interview that took place on March 1, 2004. The following discussion is intended to constitute a proper recordation of such interview in accordance with MPEP §713.04, and also to provide a full response to the Office action mailed on October 3, 2003.

The March 1, 2004 discussion focused primarily on the differences between the present invention and U.S. Patent No. 4,994,066 to Voss (hereinafter “Voss”) and U.S. Patent No. 4,955,859 to Zilber (hereinafter “Zilber”). Applicants have amended the claims to more fully characterize their invention. Applicants submit that the present invention has not been claimed or disclosed in any prior art reference, alone or in combination.

Before entry of this Amendment and Response, the status of the application is as follows:

- Claims 1-3, 11, 12, 17, and 18 are rejected under 35 U.S.C. § 102(b) as being anticipated by Voss.
- Claims 4, 5, 7-9, 38-42, 44, 45, and 47-51 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Voss in view of Zilber.
- Claims 6 and 43 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Voss in view of Zilber and U.S. Patent No. 5,246,445 to Yachia *et al.* (hereinafter “Yachia”).
- Claim 10 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Voss in view of U.S. Patent No. 5,269,802 to Garber (hereinafter “Garber”).
- Claim 46 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Voss in view of Zilber and Garber.

Claim 4 has been canceled without prejudice to its subsequent reintroduction into this case or its introduction into a related application. Claims 1, 5, 38, and 51 have been amended.

Claim 1 has been amended to include the subject matter of now-canceled claim 4. Claim 5 has been amended to correct its dependency. Claims 38 and 51 have been amended to more clearly describe the nature of the claimed invention. Applicants submit that the amendments introduce no new matter. Upon entry of this paper, claims 1-3, 5-18, and 38-51 will be pending and under consideration.

Rejection Under 35 U.S.C. §102(b)

Claims 1-3, 11, 12, 17, and 18 are rejected under 35 U.S.C. § 102(b) as being anticipated by Voss. Applicants respectfully traverse with respect to the claims, as amended.

Independent claim 1 is amended to include the subject matter of now-canceled claim 4, which was not rejected over Voss. Amended independent claim 1 recites, in part, a stent that includes first and second terminal ends and a wall disposed between each terminal end. Each terminal end has an outside cross-sectional diameter that is greater than an intermediate outside cross-sectional diameter, and the outer surface of the wall tapers down from each terminal end to at least one intermediate location. At least one of the terminal ends includes a retention ring that has an expanded ring state and a collapsed ring state. The retention ring spontaneously reverts from the collapsed ring state to the expanded ring state. When in the expanded ring state, the retention ring extends axially from the wall of the stent.

Voss appears to disclose a stent comprising a cylindrical conduit 12 having a conically shaped flange 14 at a first end and an annularly shaped flange 16 at a second end. See Voss, col. 3, lines 59-63, and FIGS. 1 and 5. The shape of the conically shaped flange can be changed into

“a compact arrangement for traversing the urethral path.” See Voss, col. 5, lines 40-44, and FIG. 7. Voss does not, however, teach or suggest a *retention ring* that has an expanded ring state and a collapsed ring state. Nor does Voss teach or suggest a stent having a wall that tapers from each terminal end to at least one intermediate location. Thus, the stent of the present invention is not anticipated by Voss.

In view of the foregoing, Applicants submit that independent claim 1, along with claims 2, 3, 11, 12, 17, and 18, which depend directly therefrom, are not anticipated by Voss.

Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

Rejections Under 35 U.S.C. §103(a)

1. Claims 4, 5, 7-9, 38-42, 44, 45, and 47-51 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Voss in view of Zilber. Applicants have canceled claim 4, rendering the rejection of this claim moot. Applicants respectfully traverse with respect to the remaining claims, as amended.

Amended independent claim 1, from which claims 5 and 7-9 depend, and amended independent claims 38 and 51 are directed toward stents that include first and second terminal ends and a wall disposed between each terminal end. Each terminal end has an outside cross-sectional diameter that is greater than an intermediate outside cross-sectional diameter, and the outer surface of the wall tapers down from each terminal end to at least one intermediate location. At least one of the terminal ends includes a retention ring that has an expanded ring state and a collapsed ring state. When in the expanded ring state, the retention ring extends axially from the wall of the stent.

Zilber appears to disclose a stent 10 comprising a tubular body 12 having a frustoconically shaped flange 14 at the upper end 16 of the stent and a textured fabric outer layer 20 bonded to the tubular body 12. See Zilber, col. 3, line 68 to col. 4, line 7, and FIGS. 1 and 2. A helical spring 28 extends from the upper end of the stent to approximately one centimeter from the lower end 24 of the stent and surrounds a lumen 26 that runs through the stent. See Zilber, col. 4, lines 19-23, and FIG. 2. The helical spring does not extend into the frustoconically shaped flange 14 of the stent. See, Zilber, FIG. 2. The helical spring reinforces the lumen of the stent against "**radial compressive forces**" while allowing enough flexibility to permit the stent to conform to the bend of the prostatic urethra. See Zilber, col. 5, lines 26-30. Alternatively, a stent may include "annular reinforcing elements in parallel, spaced apart relation" to provide reinforcement. See Zilber, col. 9, lines 31-35.

As discussed above, Voss does not teach or suggest a stent including a retention ring that has an expanded ring state and a collapsed ring state. Zilber fails to cure this deficiency. According to Zilber, the helical spring 28 surrounds the lumen 26 that runs through the body of the stent 10. Zilber is silent with respect to the spring 28 having a collapsed state, therefore Zilber does not disclose a retention ring that has an expanded ring state and a collapsed ring state. Further, when implanted in a patient, the body of the stent 10 is located within the prostatic urethra. See Zilber, col. 5, lines 36-49, and FIG. 5. As discussed in Zilber, the stent includes reinforcement to resist radial stenotic pressures, thereby resisting collapse. See Zilber, col. 9, lines 10-17. If the helical spring along the body of the stent were collapsible, the stent would no longer support the prostatic urethra, and the intended function of the stent would be destroyed. Furthermore, bending a spring along its length may cause the coils of the spring to move relative

to one another, but does not collapse the coils. Thus, Zilber's disclosure of a helical spring does not teach or suggest a retention ring that has an expanded ring state and a collapsed ring state.

With respect to the Examiner's position that the spring of Zilber can be collapsed by twisting or stretching, Applicants respectfully disagree. Twisting or stretching a spring can reduce the diameter of each coil of a spring. Reducing the diameter of a spring in this manner, however, is more properly characterized as contraction or constriction, and is not the same as a retention ring that has an expanded ring state and a collapsed ring state.

Regardless of how one characterizes the reduction in diameter of a spring due to twisting or stretching, there is no motivation provided by Zilber, because Zilber does not teach or suggest twisting or stretching the stent's helical spring. The helical spring is completely encased in the wall of the stent, which would make it difficult or impossible to twist or stretch the spring. See Zilber, col. 6, lines 32-37. Thus, the diameter of the spring does not change, and Zilber does not motivate one to modify a stent to include a structure having an expanded state and a collapsed state.

Further, as discussed above, Voss also fails to teach or suggest a stent that tapers from each terminal end to at least one intermediate location. Zilber also fails to cure this deficiency. The Zilber stent includes a frustoconically shaped flange at only the upper end of the stent, not at both ends. Zilber addresses the problem of preventing stent migration into the bladder by providing a stent body with a rough, textured outer surface; Zilber does not disclose a need for another structure, such as a flange at the remaining end, to accomplish the same task. Thus, Zilber does not teach or suggest a stent that tapers from each terminal end to at least one intermediate location.

In view of the foregoing, Applicants submit that independent claims 1, 38, and 51, along with claims 5, 7-9, 39-42, 44, 45, and 47-50 which depend directly or indirectly therefrom, are patentable over Voss in view of Zilber. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

2. Claims 6 and 43 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Voss in view of Zilber and Yachia. Applicants respectfully traverse.

As discussed above, neither Voss nor Zilber, alone or in proper combination, teaches or suggests a stent that includes a wall that tapers from each terminal end to at least one intermediate location, and a retention ring that has an expanded ring state and a collapsed ring state, as recited in amended independent claim 1 and independent claim 38, from which claims 6 and 43 depend, respectively. Yachia fails to cure this deficiency.

Yachia appears to disclose a stent comprising a spiral of thin wire that contains one or more bulges that do not appear to be at either terminal end. See Yachia, col. 4, lines 12-21, and FIGS. 1a-1c. Nowhere does Yachia teach or suggest a stent that tapers from each terminal end to at least one intermediate location and includes a retention ring that has an expanded ring state and a collapsed ring state.

In view of the foregoing, Applicants submit that claims 6 and 43 are patentable over Voss in view of Zilber and Yachia. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

3. Claim 10 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Voss in view of Garber. Applicants respectfully traverse with respect to the claims, as amended.

As discussed above, Voss does not teach or suggest a stent that includes a wall that tapers from each terminal end to at least one intermediate location, and a retention ring that has an expanded ring state and a collapsed ring state, as recited in amended independent claim 1, from which claim 10 depends. Garber fails to cure this deficiency.

Garber appears to disclose a stent comprising a first ring 12 coupled to a second ring 14 by a plurality of connecting arms 16. See Garber, col. 4, lines 43-48, and FIGS. 1, 2. The rings and arms are made of a material of sufficient hardness to prevent collapsing of the stent. See Garber, col. 5, lines 14-18. Therefore, Garber does not teach or suggest a retention ring having an expanded ring state and a collapsed ring state. Additionally, Garber does not teach or suggest a stent that includes a wall that tapers from each terminal end to at least one intermediate location, as Garber has no walls.

In view of the foregoing, Applicants submit that claim 10, which depends directly from amended claim 1, is patentable over Voss in view of Garber. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

4. Claim 46 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Voss in view of Zilber and Garber. Applicants respectfully traverse.

As discussed above, Voss, Zilber, and Garber, alone or in proper combination, do not teach or suggest a stent that includes a wall that tapers from each terminal end to at least one intermediate location, and a retention ring that has an expanded ring state and a collapsed ring state, as recited in independent claim 38, from which claim 46 depends. Therefore, Applicants submit that claim 46 is patentable over Voss in view of Zilber and Garber. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

CONCLUSION

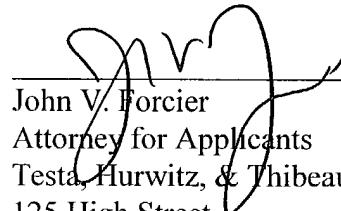
In view of the foregoing, Applicants respectfully request reconsideration, withdrawal of all grounds of rejection, and allowance of claims 1-3, 5-18, and 38-51 in due course. The Examiner is invited to contact Applicants' undersigned representative by telephone at the number listed below to discuss any outstanding issues.

Respectfully submitted,

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